



1617

PATENT
Customer No. 22,852
Attorney Docket No. 07579.0006-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
KELLY, Graham Edmund) Group Art Unit: 1617
)
Application No.: 09/986, 509) Examiner: Edward J. WEBMAN
)
Filed: November 9, 2001)
)
For: TREATMENT OR PREVENTION OF)
MENOPAUSAL SYMPTOMS)

02/05/2004 HROCHA1 00000004 060916 09986509

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

01 FC:1006 100.00 DA

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents listed on the attached Form PTO 1449. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Please charge our Deposit Account No. 06-0916 the fee of \$180.00 as specified by Section 1.17(p).

Applicant also wishes to direct the Office's attention Interference Proceeding No. 104,576 involving the Gorbach U.S. Patent No. 5,498,631 ("the '631"). In that interference, Stanley Gorbach was the senior party. The junior party, Graham Edmund Kelly, one of the inventors in this application, successfully argued the priority of U.S. Application Serial No.

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08/910,837. Thus, to the extent that the presently pending claims are similar to the Kelly claims in interference, the '631 Gorbach patent is not a proper reference under Section 102.

Finally, the Applicant also submits the following declarations obtained from opposition proceedings on patents related to this patent application in Australia and New Zealand. The following documents from these proceedings were previously submitted to the USPTO in possibly related applications. In the Information Disclosure Statement filed on April 25, 2002, for this application the Applicant disclosed the submission of these documents in the parent application. The Applicant now includes them on the attached Form PTO 1449.

1. Statutory Declaration of Joseph Nicolas Van Haaster.
2. Statutory Declaration of Norbert Krause.
3. Statutory Declaration of Hubert Regtop.
4. Statutory Declaration of Kerry Martin Bone.
5. Statutory Declaration of Nancy Beckham.
6. Statutory Declaration of G. Clements.
7. Statutory Declaration of Fiona Bathgate.
8. Statutory Declaration of Julie Hill.
9. Statutory Declaration of Ngaire Petit-Young.
10. Statutory Declaration of Jennifer Carpinelli.

Copies of the listed documents, including any copending patent applications, are attached. Schultz, in German, and Deschamps-Vallet, in French, have certified English translations attached. Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

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This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

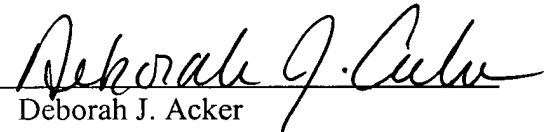
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Please charge the fee of \$180, as specified by Section 1.17(p), to our Deposit Account No. 06-0916.

Respectfully submitted,

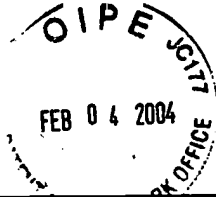
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Dated: February 3, 2004

By: 
Deborah J. Acker
Reg. No. 48,916

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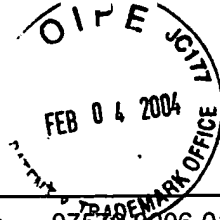


INFORMATION DISCLOSURE CITATION

Atty. Docket No.	07579.0006-01000	Serial No.	09/986,509
Applicant	KELLY, Graham Edmund		
Filing Date	November 9, 2001	Group:	1617

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	2002 0035074-A1		Kelly			03/21/2002
	3,471,520	10/07/1969	Irmscher et al.			
	3,535,344	10/20/1970	Irmscher et al.			
	3,973,608	08/10/1976	Umezawa et al.			
	4,157,984	06/12/1979	Zilliken			
	4,200,692	04/29/1980	Puls et al.			
	4,264,509	04/28/1981	Zilliken			
	4,301,251	11/17/1981	Rumyantseva et al.			
	4,366,082	12/28/1982	Zilliken			
	4,428,876	01/31/1984	Iwamura			
	4,814,346	03/21/1989	Albert et al.			
	5,247,102	09/21/1993	Kállay et al.			
	5,320,949	06/14/1994	Shen			
	5,352,384	10/04/1994	Shen			
	5,506,211	04/09/1996	Barnes et al.			
	5,516,528	05/14/1996	Hughes et al.			
	5,530,112	06/25/1996	Greenshields et al.			
	5,547,866	08/20/1996	Durzan et al.			
	5,554,519	09/10/1996	Weber et al.			
	5,569,459	10/29/1996	Shlyankevich			
	5,637,561	06/10/1997	Shen et al.			
	5,639,785	06/17/1997	Kung			

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
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INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

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Filing Date	November 9, 2001	Group:	1617

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,679,806	10/21/1997	Zheng et al.			
	5,700,669	12/23/1997	Hanson et al.			
	5,702,752	12/30/1997	Gugger et al.			
	5,726,034	03/10/1998	Bryan et al.			
	5,733,926	03/31/1998	Gorbach			
	5,763,389	06/09/1998	Shen et al.			
	5,789,581	08/04/1998	Matsuura et al.			
	5,792,503	08/11/1998	Gugger et al.			
	5,804,234	09/08/1998	Suh et al.			
	5,830,887	11/03/1998	Kelly			
	5,942,539	08/24/99	Hughes, Jr. et al.			

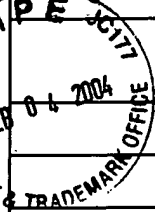
FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	AU-B-80655/87 ✓	05/05/88	Australia			
	AU 199873072 A1 ✓	09/30/1999	Australia			
	AU-A-10227/95	7/27/1995	Australia			
	AU 20027714 A1 ✓	11/23/2000	Australia			
	EP 0129667 A1 ✓	01/02/1985	Europe			
	EP 0135172 A2 ✓	03/27/1985	Europe			
	EP 0136569 A2 ✓	04/10/1985	Europe			

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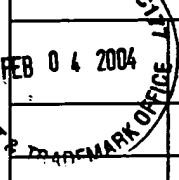
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
EP 0 671 170 A1 ✓	09/13/1995	Europe			
EP 0 795 553 A1 ✓	09/17/1997	Europe			
EP 0 906 761 A2 ✓	04/07/1999	Europe			
GB 1482238 ✓	08/10/1977	Great Britain			
GB 1 495 189 A ✓	12/14/1977	Great Britain			
JP S50-0035393 ✓	04/04/1975	Japan			Abstract
JP S50-101360 A ✓	08/11/1975	Japan			Abstract
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JP H09-067362 A ✓	03/11/1997	Japan			Abstract

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Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
JP H10-059956-A ✓	03/03/1998	Japan			Abstract
WO 91/14429 A1 ✓	10/03/1991	PCT			
WO 95/03293 A1 ✓	02/02/1995	PCT			
WO 96/10341 A1 ✓	04/11/1996	PCT			
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WO 98/52546 A1 ✓	11/26/1998	PCT			
WO 98/56373 ✓	12/17/1998	PCT			
WO 99/37633 A1 ✓	07/29/1999	PCT			Abstract
WO 99/43335 A1 ✓	09/02/1999	PCT			
WO 00/03707 A1 ✓	01/27/2000	PCT			Abstract
WO 00/62765 A2 ✓	10/26/2000	PCT			
WO 00/66576 A1 ✓	11/09/2000	PCT			

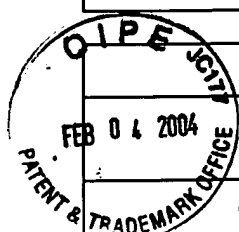
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	Adlercreutz, H. et al., "Effect of Dietary Components, Including Lignans and Phytoestrogens, on Enterohepatic Circulation and Liver Metabolism of Estrogens and on Sex Hormone Binding Globulin (SHBG)," <i>J. steroid Biochem</i> , Vol. 27, No. 4-6, pp. 1135-1144 (1987).
	Akkad, Andrea A. et al., "Abnormal Uterine Bleeding on Hormone Replacement: The Importance of Intrauterine Structural Abnormalities," <i>Obstetrics & Gynecology</i> , Vol. 86, pp. 330-334 (1995).
	Al-Maharik, N.I. et al., "Synthesis of C-C-Bridged Bis-Isoflavones," <i>J. Org. Chem.</i> , Vol. 65, pp. 2305-2308, (2000).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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<input checked="" type="checkbox"/>	Anderson et al. "Biphasic Effects of Genistein on Bone Tissue in the Ovariectomized, Lactating Rat Model," P.S. E. B. M. Vol. 217, pp. 345-350, (1998).
<input checked="" type="checkbox"/>	Bannerjee et al., "Polarography of Flavanone and Isoflavone", J. Electrochem. Soc. India, Vol. 47, No. 4, pp. 237-244, (October 1998).
<input checked="" type="checkbox"/>	Beylot "Clinical signs of skin ageing." Revue Francaise de Gynecologie et d'Obstetrique, (1991) 86/6 (433-441) ISSN: 0035-290X.
<input checked="" type="checkbox"/>	Bezuidenhoudt, B.C.B. et al., "Synthesis of Isoflavanoid Oligomers Using a Pterocarpan as Inceptive Electrophile," J. Chem. Soc. Perkin Transactions I, pp. 2767-2778.
<input checked="" type="checkbox"/>	Bingham, S.A. et al., "Phyto-oestrogens: where are we now?," British Journal of Nutrition, Vol.79, pp.393-406.
<input checked="" type="checkbox"/>	Bradley, P.R. (Ed.), "Contents" and "Index," in <i>British Herbal Compendium, Volume 1: A handbook of scientific information on widely used plant drugs</i> , British Herbal Medicine Association, Bournemouth, Dorset, pp. 5, 231-239, (1992).
<input checked="" type="checkbox"/>	Burali, C. et.al., "Synthesis and Anti-Rhinovirus Activity of Halogen-Substituted Isoflavenes and Isoflavans," <i>Europ. J. of Medicinal Chemistry</i> , Editions Scientifique Elsevier, Paris, FR, 22(2):119-123 (April 1987).
<input checked="" type="checkbox"/>	Buzzell, R.I. et al., "Inheritance of Flavonoid Glycosides in Soybeans," <i>Can. J. Genet. Cytol.</i> , Vol. 15, pp. 865-867, (1973).
<input checked="" type="checkbox"/>	Cassady, J.M. et al., "Use of a Mammalian Cell Culture Benzo(a)pyrene Metabolism Assay for the Detection of Potential Anticarcinogens from Natural Products: Inhibition of Metabolism by Biochanin A, an Isoflavone from <i>Trifolium pratense</i> L, <i>Cancer Research</i> , Vol. 48 (22), pp. 6257-6261, (November 1998).
<input checked="" type="checkbox"/>	Chang et al., "Metabolites of daidzein and genistein and their biological activities." <i>Journal of Natural Products</i> (1995), 58(12), pp. 1901-5, ISSN: 0163-3864.
<input checked="" type="checkbox"/>	Collins, B.M. et al., "The estrogenic and antiestrogenic activities of phytochemicals with the human estrogen receptor expressed in yeast," <i>Steroids</i> , Vol. 62, pp. 365-372, (April 1997).
<input checked="" type="checkbox"/>	Deschamps-Vallet, C. et al., "Transformation Du Cation Isoflavylum en Phenyl-3 Coumarines, Isoflavenes-3 et Isoflavannes," <i>Tetrahedron Letters</i> , 24(37):3993-3996 (1983).
<input checked="" type="checkbox"/>	Dewick, P.M. "5: Isoflavonoids," <i>The Flavonoids: Advances in Research Since 1986</i> , Ed. by J. B. Harborne, Published by Chapman & Hall, London, pp. 117-138.

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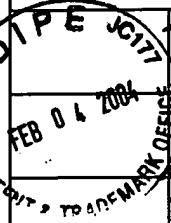
✓	Ellis, G.P. (ed.); "Chromenes, Chromanones, and Chromones"; pages 256-260; John Wiley & Sons, 1977.
✓	Evans, M. et al., "Hormone Replacement Therapy: Management of Common Problems," Mayo Clin. Proc. Vol. 70, pp. 800-805, (1995).
✓	Fanti et al. "The Phytoestrogen Genistein Reduces Bone Loss in Short-Term Ovariectomized Rats," <i>Osteoporosis Int.</i> , Vol. 8, pp. 274-281, (1998).
✓	Gaynor, J.D. et al., "HPLC Separation and Relative Quantitation of Kaempferol Glycosides in Soybean," <i>Chromatographia</i> , Vol. 25, No. 12, pp. 1049-1053, (December 1988).
✓	Hodgson, J. et al., "Supplementation with isoflavonoid phytoestrogens does not alter serum lipid concentrations: a randomised controlled trial in humans," <i>Journal of Nutrition</i> , 128: 728-332 (1998).
✓	Inoue, N., 1964, "Studies of Synthetic Isoflavones. V. The Reduction of Isoflavone," originally from <i>Bull. Chem. Soc. Japan</i> , May 1964, 37(5): 601-605, cited in <i>STN International</i> , <i>CAPLUS database</i> , (Columbus, Ohio), No. 61: 32297 (2 pages).
✓	Joannou, G.E. et al., "A Urinary Profile Study of Dietary Phytoestrogens. The Identification and Mode of Metabolism of New Isoflavonoids," <i>J. Steroid Biochem. Molec. Biol.</i> , Vol. 54, No. 3/4, pp. 167-184, (1995).
✓	Jurd, L. et al.; "Phenolic and Quinoidal Constituents of <i>Dalbergia Retusa</i> ," <i>Tetrahedron Letters</i> , Vol. 21, pages 2149-2152; (1972).
✓	Kao, Y., et al., "Molecular Basis of the Inhibition of Human Aromatase (Estrogen Synthetase) by Flavone and Isoflavone Phytoestrogens: A Site-directed Mutagenesis Study," <i>Environmental Health Perspectives</i> , Vol. 106, No. 2, pp. 85-92 (1998).
✓	Kelly et al., "Metabolites of dietary (soya) isoflavones in human urine," <i>Clinica Chimica Acta</i> 223(1-2), pp. 9-22 (December 31, 1993).
✓	Kelly, G. et al., "Standardized Red Clover Extract Clinical Monograph," Natural Products Research Consultants, Inc., Seattle, WA, pp. 3-12, (1998).
✓	Lamberton, et al., "Catalytic Hydrogenation of Isoflavones. the Preparation of (±)-Equol and Related Isoflavans", <i>Aust. J. Chem.</i> Vol. 31, pp. 455-457, (February 1978).
✓	Liepa, A.J. "A Synthesis of Hydroxylated Isoflavylium Salts and Their Reduction Products", <i>Aust. J. Chem.</i> , Vol. 34, pp. 2647-2655, (1981).
✓	Liu, Y. et al., "Abstract No. 78763p; Effects of solid dispersion of diadzein on the blood pressure of spontaneously hypersensitive rats," <i>Chemical Abstracts</i> , Vol. 115, No. 8, p. 466 (Aug. 26, 1991).

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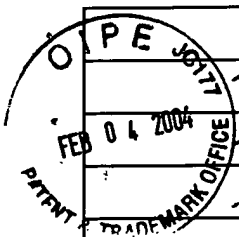
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	Mäkelä, S., et al., "Inhibition of 17 β -Hydroxysteroid Oxidoreductase by Flavonoids in Breast and Prostate Cancer Cells," pp. 310-316 (1998).
	Mazur et al.; "Natural and anthropogenic environmental oestrogens: the scientific basis for risk assessment* -Naturally occurring oestrogens in food," <i>Pure & Appl. Chem.</i> 70(9), pp. 1759-1776 (1998).
	Mazur et al., "Isoflavonoids and lignans in legumes: Nutritional and health aspects in humans," <i>Nutritional Biochemistry</i> 9, pp. 193-200 (1998).
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	Sener, A.B., et al., "The effects of hormone replacement therapy on uterine fibroids in postmenopausal women," <i>Fertility and Sterility</i> , Vol. 65, No. 2, pp. 354-357 (1996).
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	Statutory Declaration of Fiona Bathgate, declared March 24, 1998, 4 pages.

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<input checked="" type="checkbox"/>	Statutory Declaration of Jennifer Carpinelli, declared October 21, 1998, 2 pages.
<input checked="" type="checkbox"/>	Statutory Declaration of G. Clements, declared January 27, 1999, 2 pages.
<input checked="" type="checkbox"/>	Statutory Declaration of Julie Hill, declared April 4, 1998, 2 pages.
<input checked="" type="checkbox"/>	Statutory Declaration of Norbert Krause, declared November 5, 1998, 23 pages.
<input checked="" type="checkbox"/>	Statutory Declaration of Ngaire Petit-Young, declared November 5, 1998, 3 pages.
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<input checked="" type="checkbox"/>	Szabo et al., 1973, "The Selective Reduction of Isoflavon," <i>Tetrahedron Letters</i> , 19: 1659-1662.
<input checked="" type="checkbox"/>	Troisi, R.J., et al., "Menopause, Postmenopausal Estrogen Preparations and the Risk of Adult-Onset Asthma," <i>Am J Respir Crit Care Med</i> , Vol. 152, pp. 1183-1188 (1995).
<input checked="" type="checkbox"/>	Wähälä, K. et al., "Hydrogen Transfer Reduction of Isoflavones," <i>Heterocycles</i> , 28(1):183-186 (1989).
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<input checked="" type="checkbox"/>	Yahara, S. et al., "Isoflavan and Related Compounds from <i>Dalbergia odorifera</i> ." <i>Chem, Pharm. Bull.</i> 37(4): 979-987 (April 1989).

Examiner	Date Considered
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